

AMENDED IN SENATE MARCH 25, 2008

SENATE BILL

No. 1307

Introduced by Senator Ridley-Thomas

February 20, 2008

An act to amend ~~Section 4034~~ of Sections 4034, 4163, and 4163.5 of, and to add Sections 4163.2 and 4163.3 to, the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 1307, as amended, Ridley-Thomas. Pharmacy: pedigree.

Existing law, the Pharmacy Law, provides for the licensure and regulation of the practice of pharmacy and the sale of dangerous drugs or dangerous devices by the California State Board of Pharmacy, in the Department of Consumer Affairs. Under existing law, on and after January 1, 2009, pedigree means an electronic record containing information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer, through acquisition and sale by one or more wholesalers, manufacturers, or pharmacies, until final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug. On and after January 1, 2009, existing law prohibits a wholesaler or pharmacy from selling, trading, or transferring a dangerous drug without a pedigree ~~and prohibits a wholesaler or pharmacy~~ or from acquiring a dangerous drug without receiving a pedigree. Existing law, on and after January 1, 2009, requires that a pedigree include certain information, including, but not limited to, the source of the dangerous drug and the trade or generic name of the drug. Existing law authorizes the board to extend the January 1, 2009 compliance date to January 1, 2011, in specified

circumstances. Existing law makes it a crime to knowingly violate the Pharmacy Law.

This bill would *instead, on and after January 1, 2011, define a pedigree and would* require a pedigree to also include a specified unique identification number. By changing the definition of a crime, the bill would impose a state-mandated local program.

The bill would instead prohibit a wholesaler, on and after January 1, 2012, or a pharmacy, on and after July 1, 2012, from selling, trading, or transferring a dangerous drug without a pedigree or from acquiring a dangerous drug without receiving a pedigree. The bill would authorize the board to extend these compliance dates by up to one year if certain conditions are met.

The bill would authorize a manufacturer, wholesaler, or pharmacy in possession of dangerous drugs manufactured or distributed prior to the operative date of the pedigree requirements to designate these drugs as not subject to the requirements by preparing a specified written declaration under penalty of perjury. The bill would, for up to 18 months following the operative date of the pedigree requirements, authorize specified dangerous drugs to be purchased, sold, acquired, returned, or otherwise transferred, without meeting the pedigree requirements if the transfer complies with specified requirements, including a written declaration under penalty of perjury stating that the specified dangerous drug met certain requirements. Because the bill would expand the crime of perjury, the bill would impose a state-mandated local program.

The bill would require the board to promulgate regulations defining the circumstances where the board deems it appropriate for manufacturers, wholesalers, or pharmacies, to infer the contents of a case, pallet, or other aggregate of individual units, packages, or containers of dangerous drugs, from a unique identifier associated with the case, pallet, or other aggregate. The bill would declare the intent of the Legislature in this regard.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 4034 of the Business and Professions Code is amended to read:

4034. (a) "Pedigree" means a record, in electronic form, containing information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer, through acquisition and sale by one or more wholesalers, manufacturers, or pharmacies, until final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug. The pedigree shall be created and maintained in an interoperable electronic system, ensuring compatibility throughout all stages of distribution.

(b) A pedigree shall include all of the following information:

(1) The source of the dangerous drug, including the name, the federal manufacturer's registration number or a state license number as determined by the board, and principal address of the source.

(2) The trade or generic name of the drug, the quantity of the dangerous drug, its dosage form and strength, the date of the transaction, the sales invoice number, the container size, the number of containers, the expiration dates, and the lot numbers.

(3) The business name, address, and the federal manufacturer's registration number or a state license number as determined by the board, of each owner of the dangerous drug, and the dangerous drug shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug.

(4) A certification under penalty of perjury from a responsible party of the source of the dangerous drug that the information contained in the pedigree is true and accurate.

(5) The unique identification number described in subdivision (i).

(c) A single pedigree shall include every change of ownership of a given dangerous drug from its initial manufacture through to its final transaction to a pharmacy or other person for furnishing, administering, or dispensing the drug, regardless of repackaging or assignment of another National Drug Code (NDC) Directory number.

(d) A pedigree shall track each dangerous drug at the smallest package or immediate container distributed by the manufacturer,

1 received and distributed by the wholesaler, and received by the
2 pharmacy or another person furnishing, administering, or
3 dispensing the dangerous drug.

4 (e) Any return of a dangerous drug to a wholesaler or
5 manufacturer shall be documented on the same pedigree as the
6 transaction that resulted in the receipt of the drug by the party
7 returning it.

8 (f) If a licensed health care service plan, hospital organization,
9 and one or more physician organizations have exclusive contractual
10 relationships to provide health care services, drugs distributed
11 between these persons shall be deemed not to have changed
12 ownership.

13 (g) The following transactions are not required to be recorded
14 on a pedigree:

15 (1) The provision of samples of dangerous drugs by a
16 manufacturer's employee to an authorized prescriber, provided
17 the samples are dispensed to a patient of the prescriber without
18 charge.

19 (2) An injectable dangerous drug that is delivered by the
20 manufacturer directly to an authorized prescriber or other entity
21 directly responsible for administration of the injectable dangerous
22 drug, only for an injectable dangerous drug that by law may only
23 be administered under the professional supervision of the prescriber
24 or other entity directly responsible for administration of the drug.
25 Injectable dangerous drugs exempted from the pedigree
26 requirement by this paragraph may not be dispensed to a patient
27 or a patient's agent for self-administration, and shall only be
28 administered to the patient, as defined in Section 4016, by the
29 prescriber or other authorized entity that received the drug directly
30 from the manufacturer.

31 (3) The exemption in paragraph (2) shall expire and be
32 inoperative on January 1, ~~2010~~ 2012, unless prior to that date the
33 board receives, at a public hearing, evidence that entities involved
34 in the distribution of the injectable dangerous drugs subject to that
35 paragraph are not able to provide a pedigree in compliance with
36 all of the provisions of California law, and the board votes to
37 extend the expiration date for the exemption until January 1, ~~2011~~
38 2013. The decision as to whether to extend the expiration date
39 shall be within the sole discretion of the board, and shall not be

1 subject to the requirements of Chapter 3.5 (commencing with
2 Section 11340) of Part 1 of Division 3 of the Government Code.

3 (h) If a manufacturer, wholesaler, or pharmacy has reasonable
4 cause to believe that a dangerous drug in, or having been in, its
5 possession is counterfeit or the subject of a fraudulent transaction,
6 the manufacturer, wholesaler, or pharmacy shall notify the board
7 within 72 hours of obtaining that knowledge. This subdivision
8 shall apply to any dangerous drug that has been sold or distributed
9 in or through this state.

10 (i) “Interoperable electronic system” as used in this chapter
11 means an electronic track and trace system for dangerous drugs
12 that uses a unique identification number, established at the point
13 of manufacture, contained within a standardized nonproprietary
14 data format and architecture, that is uniformly used by
15 manufacturers, wholesalers, and pharmacies for the pedigree of a
16 dangerous drug.

17 (j) The application of the pedigree requirement in pharmacies
18 shall be subject to review during the board’s sunset review to be
19 conducted as described in subdivision (f) of Section 4001.

20 (k) This section shall become operative on January 1, ~~2009~~
21 ~~2011~~. However, the board may extend the date for compliance
22 with this section and Section 4163 ~~until January 1, 2011~~, in
23 accordance with Section 4163.5.

24 *SEC. 2. Section 4163 of the Business and Professions Code is*
25 *amended to read:*

26 4163. (a) A manufacturer or wholesaler may not furnish a
27 dangerous drug or dangerous device to an unauthorized person.

28 (b) Dangerous drugs or dangerous devices shall be acquired
29 from a person authorized by law to possess or furnish dangerous
30 drugs or dangerous devices. When the person acquiring the
31 dangerous drugs or dangerous devices is a wholesaler, the
32 obligation of the wholesaler shall be limited to obtaining
33 confirmation of licensure of those sources from whom it has not
34 previously acquired dangerous drugs or dangerous devices.

35 (c) Except as otherwise provided in Section 4163.5, commencing
36 on January 1, ~~2009~~ 2012, a wholesaler ~~or pharmacy~~ may not sell,
37 trade, or transfer a dangerous drug at wholesale without providing
38 a pedigree.

(d) Except as otherwise provided in Section 4163.5, commencing on January 1, ~~2009~~ 2012, a wholesaler ~~or pharmacy~~ may not acquire a dangerous drug without receiving a pedigree.

(e) *Except as otherwise provided in Section 4163.5, commencing on July 1, 2012, a pharmacy may not sell, trade, or transfer a dangerous drug at wholesale without providing a pedigree.*

(f) *Except as otherwise provided in Section 4163.5, commencing on July 1, 2012, a pharmacy may not acquire a dangerous drug without receiving a pedigree.*

SEC. 3. Section 4163.2 is added to the Business and Professions Code, to read:

4163.2. (a) (1) A manufacturer, wholesaler, or pharmacy lawfully possessing or owning dangerous drugs manufactured or distributed prior to the operative date of the pedigree requirements, specified in Sections 4034 and 4163, may designate these dangerous drugs as not subject to the pedigree requirements by preparing a written declaration made under penalty of perjury that lists those dangerous drugs.

(2) The written declaration shall include the unique identification numbers and the dates of manufacture for each dangerous drug designated. The written declaration shall be submitted to and received by the board no later than 30 days after the operative date of the pedigree requirements. The entity or person submitting the written declaration shall also retain for a period of three years and make available for inspection by the board a copy of each written declaration submitted.

(3) The board may, by regulation, further specify the requirements and procedures for the creation and submission of these written declarations.

(b) (1) For up to 18 months following the operative date of the pedigree requirements, any dangerous drugs designated on a written declaration timely created and submitted to the board may be purchased, sold, acquired, returned, or otherwise transferred without meeting the pedigree requirements, if the transfer complies with the other requirements of this chapter.

(2) Any transfer of a dangerous drug without meeting the pedigree requirements shall be accompanied by a written declaration made under penalty of perjury by a responsible party of the transferring entity or person stating that the dangerous drug, identified by its unique identification number and date of

1 *manufacture, met the requirements of subdivision (a) and the*
2 *written declaration prepared pursuant to subdivision (a) shall be*
3 *attached to this written declaration.*

4 *(3) Both the transferring and receiving parties shall retain for*
5 *a period of three years and make available for inspection by the*
6 *board a copy of each written declaration.*

7 *(4) The board may, by regulation, further specify the*
8 *requirements and procedures for these transfers and the necessary*
9 *documentation.*

10 *(5) The board may, by regulation, further extend beyond 18*
11 *months the period for transfers of nonpedigreed drugs, either for*
12 *all drugs or for specified categories or subcategories of drugs.*

13 *SEC. 4. Section 4163.3 is added to the Business and Professions*
14 *Code, to read:*

15 *4163.3. (a) It is the intent of the Legislature that participants*
16 *in the distribution chain for dangerous drugs, including*
17 *manufacturers, wholesalers, or pharmacies furnishing,*
18 *administering, or dispensing dangerous drugs, distribute and*
19 *receive electronic pedigrees, and verify and validate the delivery*
20 *and receipt of dangerous drugs against those pedigrees at the unit*
21 *level, in a manner that maintains the integrity of the pedigree*
22 *system without an unacceptable increase in the risk of diversion*
23 *or counterfeiting.*

24 *(b) To meet this goal, the board shall, by regulation, define the*
25 *circumstances, if any, under which the board deems it appropriate*
26 *for participants in the distribution chain to infer the contents of a*
27 *case, pallet, or other aggregate of individual units, packages, or*
28 *containers of dangerous drugs, from a unique identifier associated*
29 *with the case, pallet, or other aggregate, without opening each*
30 *case, pallet, or other aggregate or otherwise individually validating*
31 *each unit.*

32 *SEC. 5. Section 4163.5 of the Business and Professions Code*
33 *is amended to read:*

34 *4163.5. The board may extend the date for compliance with*
35 *the requirement for a pedigree set forth in Sections 4034 and 4163*
36 *~~until January 1, 2011, if it determines~~ subject to the following*
37 *conditions. If the board determines that manufacturers—~~or,~~*
38 *wholesalers, or pharmacies require additional time to implement*
39 *electronic technologies to track the distribution of dangerous drugs*
40 *within the state, the board may delay the operative date of Sections*

1 4034 and 4163 by up to one year for any or all of these participants
2 in the distribution chain, to any date up to January 1, 2012, for
3 manufacturers, to any date up to January 1, 2013, for wholesalers,
4 and to any date up to July 1, 2013, for pharmacies. A determination
5 by the board to extend the deadline for providing pedigrees shall
6 not be subject to the requirements of Chapter 3.5 (commencing
7 with Section 11340) of Part 1 of Division 3 of Title 2 of the
8 Government Code.

9 ~~SEC. 2.~~

10 SEC. 6. No reimbursement is required by this act pursuant to
11 Section 6 of Article XIII B of the California Constitution because
12 the only costs that may be incurred by a local agency or school
13 district will be incurred because this act creates a new crime or
14 infraction, eliminates a crime or infraction, or changes the penalty
15 for a crime or infraction, within the meaning of Section 17556 of
16 the Government Code, or changes the definition of a crime within
17 the meaning of Section 6 of Article XIII B of the California
18 Constitution.